

08-05-03

125



DOCKET NO.: ISIS-3561

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Clarence Frank Bennett, et al.

Confirmation No.: 6344

Application No.: 09/315,292

Group Art Unit: 1635

Filing Date: May 20, 1999

Examiner: Jane J. Zara

**For: COMPOSITIONS AND METHODS FOR THE PULMONARY DELIVERY OF
NUCLEIC ACIDS**

EXPRESS MAIL LABEL NO: EV325643018US

DATE OF DEPOSIT: August 22, 2003

EV325643018US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☐ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or

before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☒ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☒ Certification in Accordance with § 1.97(e) is attached;

or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith

EXCEPT THAT:


- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☐ Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. _____, filed _____.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Enclosed is a copy of the EPO Supplementary Partial European Search Report dated July 16, 2003 (number 305 on the Form PTO-1449), which indicates the references considered to be relevant.

- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ There are no listed references which are not in the English language.

Date: Aug. 22, 2003



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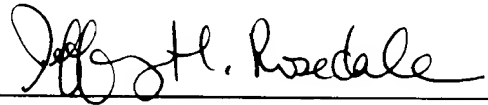
CERTIFICATION UNDER 37 CFR § 1.97(e)

In accordance with 37 CFR § 1.97(e), certification is hereby made that:

- ☒ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after

making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

Date: Aug. 22, 2003



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Sheet 1 of 2

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. ISIS-3561	Application No. 09/315,292
	Applicant Clarence Frank Bennett, et al.	
	Filing Date May 20, 1999	Group 1635
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	305	Copy of the EPO Supplementary Partial European Search Report dated July 16, 2003 (EP 99 92 3251)
	306	Levesque, L., et al., "Antisense oligonucleotides targeting human protein kinase C- α inhibit phorbol ester-induced reduction of bradykinin-evoked calcium mobilization in A549 cells," <i>Molecular Pharm.</i> , XP-002247729, 1997 , 51, 209-216
	307	McKay, R.A., "Characterization of a potent and specific class of antisense oligonucleotide inhibitor of human protein kinase C- α expression," <i>J. of Biological Chem.</i> , XP-002247728, January 15, 1999 , 274(3), 1715-1722
	308	Nicklin, P.L., et al., "Pulmonary bioavailability of a phosphorothioate oligonucleotide (CGP 64128A): comparison with other delivery routes," <i>Pharm. Res.</i> , XP008019675, 1998 , 15(4), 583-591
	309	Nyce, J.W., "Respirable antisense oligonucleotides as novel therapeutic agents for asthma and other pulmonary diseases," <i>Exp. Opin. Invest. Drugs</i> , XP002919983, 1997 , 6(9), 1149-1156
	310	Rojanasakul, Y., et al., "Antisense inhibition of silica-induced tumor necrosis factor in alveolar macrophages," <i>XP-002247730</i> , February 14, 1997 , 272(7), 3910-3914
	311	Schreier, H., "Pulmonary (poly)peptide and (poly)nucleic acid delivery," <i>Advanced Drug Delivery Rev.</i> , XP002919984, 1996 , 19, 1-2
	312	Wu-Pong, S., et al., "Airway-to-biophase transfer of inhaled oligonucleotides," <i>Advanced Drug Delivery Rev.</i> , XP002919982, 1996 , 19, 47-71

EXAMINER	DATE CONSIDERED
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U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	313	WO 93/19203	09/30/93	PCT		
	314	WO 99/11778	03/11/99	PCT		

EXAMINER	DATE CONSIDERED
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